General

Guideline Title

Interpretive diagnostic error reduction in surgical pathology and cytology: guideline from the College of American Pathologists Pathology and Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology.

Bibliographic Source(s)

Nakhleh RE, NosÃ© V, Colasacco C, Fatheree LA, Lillemoe TJ, McCrory DC, Meier FA, Otis CN, Owens SR, Raab SS, Turner RR, Ventura CB, Renshaw AA. Interpretive diagnostic error reduction in surgical pathology and cytology: guideline from the College of American Pathologists Pathology and Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology. Arch Pathol Lab Med. 2016 Jan;140(1):29-40. [148 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The grades for strength of recommendations (Strong recommendation, Recommendation, Expert consensus opinion, No recommendation) are defined at the end of the "Major Recommendations" field.

Guideline Statements

1. Anatomic pathologists should develop procedures for the review of pathology cases to detect disagreements and potential interpretive errors, and to improve patient care. (Recommendation)
2. Anatomic pathologists should perform case reviews in a timely manner to have a positive impact on patient care. (Recommendation)
3. Anatomic pathologists should have documented case review procedures that are relevant to their practice setting. (Expert Consensus Opinion)
4. Anatomic pathologists should continuously monitor and document the results of case review. (Expert Consensus Opinion)
5. If pathology case reviews show poor agreement within a defined area, anatomic pathologists should take steps to improve agreement. (Expert Consensus Opinion)

Definitions

Strength of Recommendations*

College of American Pathologists (CAP) Designation	Recommendation	Rationale
Strong Recommendation	Recommend For or Against a particular pathology review practice (Can include must or should)	Supported by high (convincing) or intermediate (adequate) quality of evidence and clear benefit that outweighs any harms.
Recommendation	Recommend For or Against a particular pathology review practice (Can include should or may)	Some limitations in quality of evidence (intermediate [adequate] or low [inadequate]), balance of benefits and harms, values, or costs, but panel concludes that there is sufficient evidence to inform a recommendation.
Expert Consensus Opinion	Recommend For or Against a particular pathology review practice (Can include should or may)	Serious limitations in quality of evidence (low [inadequate] or insufficient), balance of benefits and harms, values, or costs, but panel consensus is that a statement is necessary.
No Recommendation	No recommendation for or against a particular pathology review practice	Insufficient evidence, confidence, or agreement to provide a recommendation

*Adapted from Teutsch et al., with permission from Macmillan Publishers Ltd. Modified by the CAP Pathology and Laboratory Quality Center.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Any disease or condition requiring surgical pathology or cytology evaluation

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Pathology

Intended Users

Clinical Laboratory Personnel

Health Care Providers

Physicians

Guideline Objective(s)

- To develop, through a systematic review of the literature, recommendations for the review of pathology cases to detect or prevent interpretive diagnostic errors
- To address the overarching question, "What are the most effective ways to reduce interpretive diagnostic errors in anatomic pathology?" The key questions that the panel addressed were:
    - Does targeted review (done at either the analytic or the postanalytic phase) of surgical pathology or cytology cases (slides and/or reports) reduce the error rate (often measured as amended reports) or increase the rate of interpretive error detection compared with no review, random review, or usual review procedures?
    - What methods of selecting cases for review have been shown to increase/decrease the rate of interpretive error detection compared with no review, random review, or usual review procedures?

Target Population

Patients with any disease or condition requiring surgical pathology or cytology evaluation

Interventions and Practices Considered

1. Development of procedures for the review of pathology cases
2. Conducting case reviews in a timely manner
3. Documentation of case review procedures
4. Continuous monitoring and documentation of case review results
5. Steps to improve agreement in pathology case reviews

Major Outcomes Considered

- Discrepancy rate
- Diagnostic thinking
- Therapeutic efficacy
- Patient outcome efficacy
- Efficiency or cost

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Systematic Literature Review and Analysis

A systematic literature search was completed for relevant evidence in MEDLINE using both OvidSP and PubMed (January 1, 1992, to October 31, 2012). The search strategy included medical subject headings (MeSH) and text words to capture the general concepts of pathology and

quality (e.g., pathology, surgical; pathology, clinical; pathology and quality improvement; quality assurance, health care; quality control; reproducibility of results), and a targeted concept of slide/case review. MEDLINE searches were supplemented with a search of Google Scholar, a search for meeting abstracts (2008–2012) using both Biosis Previews and hand searching, and a focused hand search of identified pathology journals (2008–2012). An update of the OvidSP search was conducted through October 2013. All searches were limited to human studies published in English. Reference lists of included articles were also reviewed for relevant reports. Detailed information regarding the literature search strategy can be found in the supplemental digital content (SDC) (see the "Availability of Companion Documents" field).

Eligible Study Designs

All study designs were included in the initial literature search. In addition to journal articles, the search identified monographs and meeting abstracts. During evidence review, articles that did not present new evidence were excluded, including letters, commentaries, and editorials.

Inclusion Criteria

Published studies were selected for full-text review if they met each of the following criteria:

1. English-language articles/documents that addressed surgical pathology or cytology studies and provided data or information relevant to one or more key questions; and
2. Original research addressing pathology case reviews

Exclusion Criteria

Editorials, letters, commentaries, and invited opinions were not included in the study. Articles were also excluded if the full article was not available in English, did not address any key questions, and/or focused primarily on clinical pathology studies, including all other specialties except radiology. Articles were also excluded if they were focused on any of the following: preanalytic specimen processes, noninterpretative postanalytic processes, additional diagnostic techniques, issues related to competency use of checklists, standardized language, taxonomy, or formatting.

Results

A total of 823 studies met the search term requirements. A total of 137 articles were included for data extraction.

For further details on the literature search, including MeSH terms and keywords, see the SDC (see the "Availability of Companion Documents" field).

Number of Source Documents

A total of 137 articles were included for data extraction. See Appendix A in the supplemental digital content (SDC) (see the "Availability of Companion Documents" field) for a flow chart of the literature search results.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence Ratings in the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Framework*

GRADE	Definition
High	Further research is very unlikely to change confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain.

GRADE	Definition

*Adapted from Guyatt et al., with permission from BMJ Publishing Group Ltd.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction and Management

The data elements from an included article/document were extracted by one reviewer into standard data formats and tables developed using systematic review database software (DistillerSR, Evidence Partners Inc., Ottawa, Canada); a second reviewer confirmed accuracy and completeness. In all cases, the methodologist acted as either the primary or secondary reviewer. Any discrepancies in data extraction were resolved by discussion with the methodologist. A bibliographic database was established in EndNote (Thomson Reuters, Carlsbad, CA) to track all literature identified and reviewed during the study.

Data Analysis

Rates of discrepancy and major discrepancy were described for all studies, and subgroups based on type of specimen (surgical pathology, cytopathology or both), focusing on one organ or organ system (single organ) versus multi-organ studies, and whether conducted within a single institution (internal) or reviews of cases diagnosed at a different institution (external). Studies were tested for homogeneity using Comprehensive Meta Analysis version 2.2.064. Nonparametric descriptive statistics including median, and 1st and 3rd quartiles were calculated using Excel.

Quality Assessment

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach provides a system for rating quality of evidence and strength of recommendations that is explicit, comprehensive, transparent, and pragmatic, and is increasingly being adopted by organizations worldwide. The GRADE approach examines the quality of evidence at the level of individual studies and also at the review level. GRADE was used for rating the quality of evidence. At the individual study level, the panel assessed studies according to three criteria: (1) study design rating, (2) risk of bias rating, and (3) applicability concerns. A physician-methodologist consultant experienced in systematic review and guideline development rated the quality of each study, constructed evidence tables and summary of findings tables, and, along with the panel, developed quality of evidence ratings. The quality of evidence definitions from GRADE are shown (see the "Rating Scheme for the Strength of the Evidence" field).

For further details on the analysis of the evidence, see the supplemental digital content (SDC) (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

Description of Methods Used to Formulate the Recommendations

Panel Composition

The College of American Pathologists (CAP) Pathology and Laboratory Quality Center (the Center) and the Association of Directors of Anatomic and Surgical Pathology (ADASP) convened an expert panel consisting of practicing pathologists with expertise and experience in surgical pathology. Members included practicing pathologists in the United States and Canada. The CAP and ADASP approved the appointment of the project, cochairs, and expert panel members. In addition, a physician-methodologist experienced in systematic review and guideline development consulted with the panel throughout the project.

Assessing the Strength of Recommendations

Development of recommendations requires that the panel review the identified evidence and make a series of key judgments using procedures

described in the supplemental digital content (SDC) (see the "Availability of Companion Documents" field). CAP uses a three-tier system to rate the strength of recommendations instead of the traditional two-tier approach of strong or weak recommendations. This approach is consistent with prior CAP guidelines (see the "Rating Scheme for the Strength of the Recommendations" field).

Results

The panel convened 26 times (25 by teleconference and 1 face-to-face meeting) to develop the scope, draft recommendations, review and respond to solicited feedback, and assess the quality of evidence that supports the final recommendations. A nominal group technique was employed by the panel for consensus decision-making to encourage unique input with balanced participation among group members. An open comment period was held from December 2, 2013, through January 21, 2014, during which draft recommendations were posted on the CAP Web site. Five recommendations were drafted, with strong agreement for each recommendation from the open comment period participants ranging from 87% to 93% (refer to "Outcomes" section in the SDC for full details). The expert panel modified the draft recommendations based on the feedback given during the considered judgment process.

A detailed description of the methods and systematic review used for this guideline can be found in the SDC.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations*

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Cost Analysis

Formal cost analysis or cost-effectiveness was not performed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

An independent review panel, masked to the expert panel and vetted through the conflict of interest process, provided final review of the manuscript and recommended it for approval by the College of American Pathologists (CAP). Final approval was done by the CAP Council on Scientific Affairs and Association of Directors of Anatomic and Surgical Pathology (ADASP) Executive Board.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Detection of errors may prevent unnecessary and potentially harmful therapies.
- Review of pathology cases to detect disagreements and potential interpretive errors improves the quality of patient care.
- Enhancement of collaborative diagnostic teamwork

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- The College of American Pathologists (CAP) developed the Pathology and Laboratory Quality Center as a forum to create and maintain evidence-based practice guidelines and consensus statements. Practice guidelines and consensus statements reflect the best available evidence and expert consensus supported in practice. They are intended to assist physicians and patients in clinical decision-making and to identify questions and settings for further research. With the rapid flow of scientific information, new evidence may emerge between the time a practice guideline or consensus statement is developed and when it is published or read. Guidelines and statements are not continually updated and may not reflect the most recent evidence. Guidelines and statements address only the topics specifically identified therein and are not applicable to other interventions, diseases, or stages of diseases. Furthermore, guidelines and consensus statements cannot account for individual variation among patients and cannot be considered inclusive of all proper methods of care or exclusive of other treatments. It is the responsibility of the treating physician or other health care provider, relying on independent experience and knowledge, to determine the best course of treatment for the patient. Accordingly, adherence to any practice guideline or consensus statement is voluntary, with the ultimate determination regarding its application to be made by the physician in light of each patient's individual circumstances and preferences. CAP and the Association of Directors of Anatomic and Surgical Pathology (ADASP) make no warranty, express or implied, regarding guidelines and statements, and specifically exclude any warranties of merchantability and fitness for a particular use or purpose. CAP and ADASP assume no responsibility for any injury or damage to persons or property arising out of or related to any use of this statement or for any errors or omissions.
- Because secondary review of cases detects and corrects errors, it is natural to wonder whether these data can be used to measure quality in an anatomic pathology laboratory. Such a measure would be of tremendous interest to pathologists, clinicians, employers, insurers, and patients. However, at present it is not clear how best to interpret the results of these reviews appropriately, and these results should not be

used to attempt to compare the quality of two different pathology laboratories.
- The recommendations should be tailored to the needs of the individual laboratory.

Implementation of the Guideline

Description of Implementation Strategy

The College of American Pathologists (CAP) will host an Interpretive Diagnostic Error Reduction Through Targeted Case Reviews in Surgical Pathology and Cytology Resource Web page which will include a link to the manuscript and supplemental digital content; summary of recommendations, teaching PowerPoint, and a frequently asked question (FAQ) document. The Association of Directors of Anatomic and Surgical Pathology (ADASP) Web page will include a link to the CAP guideline resource page. The guideline will be promoted and presented at various professional society meetings including the College of American Pathologists, the United States and Canadian Academy of Pathology (USCAP), and the American Society of Clinical Pathology (ASCP).

Implementation Tools

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Nakhleh RE, NosÃ© V, Colasacco C, Fatheree LA, Lillemoe TJ, McCrory DC, Meier FA, Otis CN, Owens SR, Raab SS, Turner RR, Ventura CB, Renshaw AA. Interpretive diagnostic error reduction in surgical pathology and cytology: guideline from the College of American Pathologists Pathology and Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology. Arch Pathol Lab Med. 2016 Jan;140(1):29-40. [148 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Jan

Guideline Developer(s)

Association of Directors of Anatomic and Surgical Pathology - Professional Association

College of American Pathologists - Medical Specialty Society

Source(s) of Funding

The College of American Pathologists (CAP) and the Association of Directors of Anatomic and Surgical Pathology (ADASP) provided funding for the administration of the project; no industry funds were used in the development of the guideline. All panel members volunteered their time and were not compensated for their involvement.

Guideline Committee

The College of American Pathologists (CAP) Pathology and Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology (ADASP) Expert Panel

Composition of Group That Authored the Guideline

Panel Members: Raouf E. Nakhleh, MD, Department of Laboratory Medicine and Pathology, Mayo Clinic, Jacksonville, Florida; Vania Nosé, MD, PhD, Department of Pathology, Massachusetts General Hospital, Boston; Carol Colasacco, MLIS, SCT(ASCP), Governance, College of American Pathologists, Northfield, Illinois; Lisa A. Fatheree, SCT(ASCP), Pathology and Laboratory Quality Center, College of American Pathologists, Northfield, Illinois; Tamera J. Lillemoe, MD, Hospital Pathology Associates, Abbott Northwestern Hospital, Minneapolis, Minnesota; Douglas C. McCrory, MD, MHS, Department of Medicine, Duke University, Durham, North Carolina; Frederick A. Meier, MD, Department of Pathology, Massachusetts General Hospital, Boston; Christopher N. Otis, MD, Department of Pathology, Baystate Medical Center, Springfield, Massachusetts; Scott R. Owens, MD, Department of Pathology, University of Michigan Medical School, Ann Arbor; Stephen S. Raab, MD, Department of Pathology, Memorial University of Newfoundland/Eastern Health Authority, St John's, Newfoundland, Canada; Roderick R. Turner, MD, Department of Pathology, St John's Health Center, Santa Monica, California; Christina B. Ventura, MT(ASCP), Pathology and Laboratory Quality Center, College of American Pathologists, Northfield, Illinois; Andrew A. Renshaw, MD, Department of Pathology, Homestead Hospital, Homestead, Florida

Financial Disclosures/Conflicts of Interest

Prior to acceptance on the expert panel, potential members completed the College of American Pathologists (CAP) conflict of interest disclosure process, whose policy and form require disclosure of material financial interest in, or potential for benefit of significant value from, the guideline's development or its recommendations. The potential members completed the conflict of interest disclosure form, listing any relationship that could be interpreted as constituting an actual, potential, or apparent conflict. Potential conflicts were managed by the cochairs. Everyone was required to disclose conflicts prior to beginning and continuously throughout the project's timeline. Disclosed conflicts of the expert panel members are listed in the appendix of the original guideline document. Please see the supplemental digital content (see the "Availability of Companion Documents" field) for full details on the conflict of interest policy.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Archives of Pathology & Laboratory Medicine Journal Web site .

Availability of Companion Documents

The following are available:

- Interpretive diagnostic error reduction in surgical pathology and cytology: joint guideline from the College of American Pathologists Pathology and Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology. Supplemental digital content. 2015 Mar. 23 p. Available from the College of American Pathologists (CAP) Web site .
- Interpretive diagnostic error reduction in surgical pathology and cytology. Summary of recommendations. 2016. 1 p. Available from the CAP Web site .
- Interpretive diagnostic error reduction in surgical pathology and cytology. Frequently asked questions. 2015 May 13. 3 p. Available from the CAP Web site .
- Interpretive diagnostic error reduction in surgical pathology and cytology: guideline from the College of American Pathologists (CAP) Pathology and Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology. Slide presentation. 2015 May 13. 40 p. Available from the CAP Web site .
- Guideline for interpretive diagnostic error reduction in surgical pathology and cytology. Infographic. 2015. 1 p. Available from the CAP Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on February 29, 2016. The information was verified by the guideline developer on April 8, 2016.

Copyright Statement

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